PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/BE2004/000180	21.12.2004	24.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61M5/172

Applicant
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1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/BE2004/000180

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 15

because:

☒ the said international application, or the said claims Nos. 15 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 15

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3-5,8-14
	No:	Claims	1,2,6,7
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 15 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US 2002/169636 A1 (SCHLOTTERBECK DAVID L ET AL) 14 November 2002 (2002-11-14)

D2: WO 99/10029 A (LARKINS WILLIAM T ;MANDRO MARC A (US); DEMERS JASON A (US); KAMEN) 4 March 1999 (1999-03-04)

1). The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

From D1 "a system for computer-aided intravenous delivery of drugs to a patient" is known, comprising "an infusion controller (CPU 50 in D1, see D1, paragraph 23 and figure 1) that delivers an amount of drug to a patient, a communication controller (CPU 50 in D1) connected with the infusion pumps (any of the functional modules 16, 18, 20, 22 in D1, see D1, paragraph 26 and figure 1), a session controller (CPU 50 in D1) arranged to carry out the modeling of anesthesia procedures and arranged to run a first procedure and select and run a second procedure based upon observations from a physician, a graphic user interface to display different views of the system and to accept user input (user interface device 54 in D1, see D1, paragraph 24 and figure 1), a set of interfaces (internal buses 64 in D1, see D1, paragraph 23 and figure 1) used to link the infusion controller and the session controller to views displayed by the graphical user interface (see D1, paragraph 24

+ dynamically

and figure 1), an infusion session manager (advanced programming module 14 in D1, see D1, paragraphs 23 and 29) that integrates the graphic user interface, the infusion controller, the communication controller and the session controller (see D1, figure 1) and that steers drug delivery, wherein the system contains a set of configurable written procedures to steer intravenous drug delivery, whereby said procedures have been adapted to the type of therapy, adapted to the patient's physical condition, and adapted to the type of drugs, tools and theoretical models used (see D1, paragraph 30)".

Claim 1 is thus not novel.

2.1). Claim 1 is furthermore anticipated by D2, see the passages of D2 as cited in the search report.

3). The dependent claims do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty and/or inventive step, the reasons being as follows:

Claim 2 is known from D1, see D1, paragraph 32.

The feature of claim 3 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. Claim 3 is thus not inventive.

The features defined in claims 4 and 5 are described in D2 (see D2, page 25, line 24 to page 26, line 4) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include these features in the system described in D1 in order to solve the problem posed. Claims 4 and 5 are thus not inventive.

Claim 6 is known from D1, see D1, paragraph 31.

Claim 7 is known from D1, see D1, paragraph 47.

The features defined in claims 8 to 12 represent merely several straightforward possi-

bilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. Claims 8 to 12 are thus not inventive.

The features defined in claims 13 and 14 are described in D2 (see D2, page 24, line 36 to page 25, line 23) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include these features in the system described in D1 in order to solve the problem posed. Claims 13 and 14 are thus not inventive.

4). The following deficiencies were found:

OK 4.1). The wording of the claims conflict with the provisions of Rule 67.1(iv) PCT; i.e. definitions such as "that delivers an amount of drug" (claim 1, line 6), "that steers drug delivery" (claim 1, line 28) and "administers .... a drug" (claim 8, line 26) should have been formulated as e.g. "capable of delivering and amount of drug", "capable of steering drug delivery" and "is capable of administering .... a drug" respectively.

OK 4.2). The term "possibly" used in claim 1, line 8 and in claim 11, line 8 is believed to be understood as "optionally". Such options should have been defined in dependent claims (Rule 6.4 PCT). The same argument applies with regard to "or" and "and/or" used extensively throughout the claims (Article 6 PCT).

Was ok OK 4.3). Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

4.4). The independent claim is not in the two-part form in accordance with Rule 6.3(b) PCT.

4.5). The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).